General

Guideline Title

Cervical spine collar clearance in the obtunded adult blunt trauma patient: a systematic review and practice management guideline from the Eastern Association for the Surgery of Trauma.

Bibliographic Source(s)

Patel MB, Patel MB, Humble SS, Humble SS, Cullinane DC, Cullinane DC, Day MA, Day MA, Jawa RS, Jawa RS, Devin CJ, Devin CJ, Delozier MS, Delozier MS, Smith LM, Smith LM, Smith MA, Smith MA, Capella JM, Capella JM, Long AM, Long AM, Cheng JS, Cheng JS, Leath TC, Leath TC, FalckYtter Y, FalckYtter Y, Haut ER, Haut ER, Como JJ, Como JJ. Cervical spine collar clearance in the obtunded adult blunt trauma patient: A systematic review and practice management guideline from the Eastern Association for the Surgery of Trauma. J Trauma Acute Care Surg. 2015 Feb;78(2):430-41. [100 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The strength of recommendation (strong or weak/conditional) and levels of evidence (high, moderate, low or very low) are defined at the end of the "Major Recommendations" field.

In obtunded adult blunt trauma patients, the guideline authors conditionally recommend cervical collar removal after a negative high-quality cervical spine (C-spine) computed tomography (CT) scan result alone (see Figure 3 in the original guideline document). This conditional recommendation is based on very low-quality evidence but places a strong emphasis on the high negative predictive value of high-quality CT imaging in excluding the critically important unstable C-spine injury. This recommendation is further supported by the high costs of magnetic resonance imaging (MRI) or other additional imaging. Adjunctive imaging after a high-quality CT scan increases the number of low-value diagnoses, places patients at risk for unnecessary treatment plans, puts patients with multiple injuries at risk by moving them out of the intensive care unit to the resource-limited MRI suite, and at best, results in the same clinical action of collar removal. However, the use of this approach may result in a nonzero rate of neurologic deterioration.

Definitions:

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Methodology Levels for Rating the Quality of Evidence

Quality Level	Definitions
High	Very confident that the true effect lies close to estimate of effect.
Moderate	Moderate effect; true effect is likely close to estimate of effect but may be substantially different.
Low	Limited confidence; true effect may be substantially different from estimate of effect
Very Low	Little confidence; true effect likely substantially different from estimate of effect.

GRADE â€‹â€‹Definition of Strong and Weak Recommendation

	Strong Recommendation	Weak/Conditional Recommendation
For patients	Most patients would want the recommended course of action.	Most patients would want the recommended course of action, but many would not.
For clinicians	Most patients should receive the recommended course of action.	Different choices will exist for different patients, and clinicians should help patients decide.
For policy makers	Recommended course should be adopted as policy.	Considerable debate and stakeholder involvement needed to make policy.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Obtunded blunt trauma

Guideline Category

Evaluation

Management

Clinical Specialty

Critical Care

Emergency Medicine

Internal Medicine

Neurology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To perform a systematic review and develop evidence-based recommendations that might be used to direct decision making in the removal of a cervical collar from the adult obtunded blunt trauma patient after a negative high-quality cervical spine (C-spine) computed tomography (CT) result

Target Population

Obtunded adult blunt trauma patients

Interventions and Practices Considered

1. Cervical collar removal after a negative high-quality cervical spine (C-spine) computed tomography (CT) scan result alone
2. Cervical collar removal after a negative high-quality C-spine CT result combined with adjunct imaging

Major Outcomes Considered

- Diagnostic accuracy of cervical spine (C-spine) computed tomography (CT)
- Neurological changes after cervical collar removal
- Unstable injuries
- Stable injuries
- Pressure ulcer from cervical collar
- Time to collar removal

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Study Eligibility

Inclusion criteria consisted of adult blunt trauma patients 16 years or older, who underwent cervical spine (C-spine) computed tomography (CT) with axial thickness of less than 3 mm and who were obtunded with any author-specified definition of this term (Glasgow Coma Scale [GCS] score <15, unconscious, intubated, altered mental status, unreliable examination, distracting injury, intoxication, or not meeting NEXUS guidelines).

Exclusion criteria consisted of those studies that did not specify axial CT slice thickness and those with axial slice thickness of 3 mm or greater, so as to eliminate outdated CT technique and/or equipment. Also excluded were case reports, newspaper articles, letters, comments, practice

guidelines, news, editorials, legal cases, reviews, or congresses that contained no original data. However, to ensure the search strategy did not exclude any appropriate articles, the guideline authors manually searched the references of all included and excluded publications, and did not restrict the search by publication date or language.

Interventions and Comparators

Given the lack of randomized clinical trial data and near absence of complete cohort study designs, the guideline authors anticipated and allowed partial cohort and pre-post study designs. Thus, each patient underwent a C-spine CT that was read as normal and was then retested with the comparator adjunct imaging and/or physical examination. Study design issues among intervention and comparators precluded a quantitative synthesis (estimate of treatment effect, heterogeneity assessment, meta-analysis, or full quality assessment).

Types of Critical Outcomes

As per Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, outcomes were chosen by the team and rated in importance from 1 to 9 (see Figure 1 in the original guideline document), with scores of 7 to 9 representing critical outcomes. The critical outcomes were new neurologic change resulting in paraplegia or quadriplegia after cervical collar removal and identification of an unstable injury. The latter outcome measure was subcategorized into whether it was treated with an operation or an orthotic (e.g., cervical collar).

Types of Secondary Outcomes

The secondary outcomes, in order of decreasing importance, were stable C-spine injury (subcategories, treated with operation or treated with an orthotic), post-clearance imaging, false-negative CT imaging result on re-review, pressure ulcers, and time to cervical collar removal.

Information Sources

The guideline authors conducted a systematic search using the PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials (CENTRAL) databases with no restriction on study date. This search was last run on August 15, 2013, and the search terms are listed in the supplemental digital content (see the "Availability of Companion Documents" field). Given the time elapsed between the initial search and the data extraction stage, as of May 14, 2014, eight additional recent articles were provided for additional full-text review.

Selection of Studies

After completing the electronic literature search, two independent reviewers screened titles and abstracts, applying inclusion criteria. Any reviewer discordance was conservatively resolved by inclusion into the full-text phase. The resulting studies then underwent full-text review, again by two independent reviewers, to determine appropriateness for inclusion in the quantitative synthesis phase. Any disagreement at this stage was resolved by consensus between the two reviewers and, if necessary, the addition of a third reviewer.

Number of Source Documents

12 studies were included in the qualitative synthesis. See Figure 2 in the original guideline document for a PRISMA flow diagram of the systematic review phases.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Methodology Levels for Rating the Quality of Evidence

Quality Level	Definitions
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Low	Limited confidence; true effect may be substantially different from estimate of effect

Quality Level	Definitions
Very Low	Little confidence; true effect likely substantially different from estimate of effect.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction and Management

At each stage of the systematic review, all forms used by each reviewer were entered into Web-based DistillerSR (2014 Systematic Review and Literature Review Software from Evidence Partners) and exported into Microsoft Excel for table creation.

The following data was extracted: study author, study dates (as opposed to publication dates), population demographics (age, Injury Severity Score [ISS], Glasgow Coma Scale [GCS] score, and definition of obtunded), adjunct method following cervical spine (C-spine) computed tomography (CT), type of C-spine injury (bone, ligament, spinal cord, or intervertebral disc), stability of C-spine, and treatment provided for identified injury (if any). Sex or blunt injury mechanism subtype were not captured because of the literature deficits in plausibly linking these variables to any of the defined outcome measures. Given the overlap between patient factors and secular trends (e.g., institutional protocols, slice number, machine types), both associated with optimal spatial and contrast resolution for imaging of the C-spine, the imaging data collection was limited to axial thickness (in millimeters) for CT and Tesla strength for magnetic resonance imaging (MRI). The guideline authors also aimed to capture any recognized false-negative C-spine CT radiographic interpretations on either clinical or research reassessment, cervical collar complication (e.g., pressure ulcer), and time to cervical collar clearance. The term obtunded required an operationalized definition using the terms *Glasgow Coma Scale, altered, intoxicated, intubated, unconscious, and/or unreliable exam*.

Unstable injuries were identified primarily using the system delineated by White and Punjabi and the three-column model of Denis. C-spine instability required either a fracture or fractures involving contiguous columns or levels, bone misalignment (subluxations, listhesis, interspinous widening, or splaying), or single-level ligamentous injury involving all three columns. A priori, the committee consensus of clinical judgment was that a 3 of 1,000 rate (0.3%), an upper acceptable limit for a missed unstable C-spine injury. Spinal cord injuries included spinal epidural hematomas, subdural hematomas, cord edema, or cord contusions. Nonligamentous soft tissue injury was captured, when specified. If discrepancies existed among reviewed text and figures/tables, the former was prioritized.

Risk of Bias

Given that the most consistent outcome measures reported were those of diagnostic accuracy (identification of stable or unstable injury), the guideline authors chose the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool to assess the quality of the included studies. The QUADAS-2 tool assesses four domains as follows: patient selection, index test, reference standard, and patient flow. Each domain was assessed in terms of risk of bias, and the first three domains were also assessed for applicability.

Grading the Evidence

Following the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, inconsistency of results, imprecision, and publication bias were difficult to assess because of the study design limitations of pre-post partial cohorts, resulting in an inability to perform a meta-analysis across any outcome measure. The quality of the evidence was further reduced because of indirectness of evidence relative to our wide definition of *obtunded* (population), noncomparable institutional imaging protocols (intervention and comparator), and inconsistently reported and often unavailable outcomes. Publication bias was present, as there is at least one case report noting neurologic change after collar clearance with a negative C-spine CT result. Moreover, across multiple institutions, the guideline authors have encountered at least one case of neurologic change. Thus, the quality of evidence across all outcomes is very low.

For one of the critical outcome measures, the guideline authors rated up the quality of evidence from low quality to moderate quality for magnitude of effect, given the consistently high negative predictive value (100%) of a normal C-spine CT result for the finding of an unstable C-spine injury. Despite this, the overall quality of evidence across all outcomes remains very low because of the very low-quality evidence available for our most critical outcome, neurologic change after cervical collar removal (see Table 5 in the original guideline document).

Methods Used to Formulate the Recommendations

Expert Consensus

Other

Description of Methods Used to Formulate the Recommendations

The strengths of this work included the transparent multilevel systematic dual-review of the literature, an a priori publically available protocol and PICO (Population, Intervention, Comparator, and Outcomes) question, as well as the multispecialty nature of the group. The authors were affiliated with 12 institutions, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group, as well as the Eastern Association for the Surgery of Trauma and its Guidelines Committee and represent the fields of anesthesiology, emergency medicine, general surgery, orthopedics, public health, neurocritical care, neuroradiology, neurosurgery, rehabilitation, spine surgery, surgical critical care, as well as trauma and acute care surgery.

The PICO question and protocol were registered with the PROSPERO international prospective register of systematic reviews on August 23, 2013 (Registration Number: CRD42013005461) and last revised on June 18, 2014.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations Assessment Development, and Evaluation (GRADE) â€‹â€‹Definition of Strong and Weak Recommendation

	Strong Recommendation	Weak/Conditional Recommendation
For patients	Most patients would want the recommended course of action.	Most patients would want the recommended course of action, but many would not.
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Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

All authors participated in the critical revisions to the manuscript.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Optimal management and care of obtunded adult blunt trauma patients

Potential Harms

Cervical collar removal can result in neurologic change and even paralysis, although this may be underreported in the literature.

Qualifying Statements

Qualifying Statements

- The Eastern Association for the Surgery of Trauma (EAST) is a multi-disciplinary professional society committed to improving the care of injured patients. The Ad hoc Committee for Practice Management Guideline Development of EAST develops and disseminates evidence-based information to increase the scientific knowledge needed to enhance patient and clinical decision-making, improve health care quality, and promote efficiency in the organization of public and private systems of health care delivery. Unless specifically stated otherwise, the opinions expressed and statements made in this publication reflect the authors' personal observations and do not imply endorsement by official policy of EAST.
- "Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."* These guidelines are not fixed protocols that must be followed, but are intended for health care professionals and providers to consider. While they identify and describe generally recommended courses of intervention, they are not presented as a substitute for the advice of a physician or other knowledgeable health care professional or provider. Individual patients may require different treatments from those specified in a given guideline. Guidelines are not entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results. While guidelines can be written that take into account variations in clinical settings, resources, or common patient characteristics, they cannot address the unique needs of each patient nor the combination of resources available to a particular community or health care professional or provider. Deviations from clinical practice guidelines may be justified by individual circumstances. Thus, guidelines must be applied based on individual patient needs using professional judgment.
- The guideline authors acknowledge the weakness in data quality related to imprecision, publication bias, and indirectness of evidence as well as included study design limitations. It is possible that there is a Type II error in this systematic review because of the available literature that may be populated by underpowered studies.
- The guideline authors found the term *obtunded* to have widely differing interpretations. There were no clear definitions applicable to clinicians, and there were no measures of validity or interrater reliability.

*Institute of Medicine. Clinical practice guidelines: directions for a new program. MJ Field and KN Lohr (eds) Washington, DC: National Academy Press. 1990: pg 39.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Patel MB, Patel MB, Humble SS, Humble SS, Cullinane DC, Cullinane DC, Day MA, Day MA, Jawa RS, Jawa RS, Devin CJ, Devin CJ, Delozier MS, Delozier MS, Smith LM, Smith LM, Smith MA, Smith MA, Capella JM, Capella JM, Long AM, Long AM, Cheng JS, Cheng JS, Leath TC, Leath TC, FalckYtter Y, FalckYtter Y, Haut ER, Haut ER, Como JJ, Como JJ. Cervical spine collar clearance in the obtunded adult blunt trauma patient: A systematic review and practice management guideline from the Eastern Association for the Surgery of Trauma. J Trauma Acute Care Surg. 2015 Feb;78(2):430-41. [100 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Feb

Guideline Developer(s)

Eastern Association for the Surgery of Trauma - Professional Association

Source(s) of Funding

Vanderbilt Physician-Scientist Development grant (mbp)

REDCap, UL1 TR000445 from NCATS/NIH (all authors)

Guideline Committee

Eastern Association for the Surgery of Trauma (EAST) Practice Management Guidelines Committee

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

M.B.P. is supported by the Vanderbilt Physician-Scientist Development grant, the Vanderbilt Institute for Clinical and Translational Research awards (VR1584, VR5351) via CTSA grant UL1TR000011 (NCRR/NCATS/NIH), and an EAST Trauma Foundation Research Scholarship. M.B.P. is a member of the EAST Guidelines Committee, and EAST Board of Directors, and chair of the EAST Mentoring Committee.

C.J.D. has received resident grant and educational support from Depuy Spine and Stryker Spine, is a consultant for Exparel, and serves as a defense witness.

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Y.F.-Y. is a member of the GRADE working group.

E.R.H. is the primary investigator and supported by a contract (CE-12-11-4489) from the Patient-Centered Outcomes Research Institute (PCORI) entitled "Preventing Venous Thromboembolism: Empowering Patients and Enabling Patient-Centered Care via Health Information Technology," was the primary investigator of a Mentored Clinician Scientist Development Award K08 1K08HS017952-01 from the AHRQ entitled "Does Screening Variability Make DVT an Unreliable Quality Measure of Trauma Care?", receives royalties from Lippincott, Williams & Wilkins for a book - *Avoiding Common ICU Errors*, and has given expert witness testimony in various medical malpractice cases. E.R.H. is member of the EAST Board of Directors and is chair of the EAST Guidelines Committee.

T.C.L. is supported by the Vanderbilt Institute for Clinical and Translational Research award (VR12073) via CTSA grant UL1TR000011 (NCRR/NCATS/NIH).

J.J.C. is chair of the EAST Guidelines - Trauma Task Force and a member of the EAST Guidelines Committee.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the Eastern Association for the Surgery of Trauma (EAST) Web site .

Print copies: Available from the Eastern Association for the Surgery of Trauma Guidelines, c/o Mayur B. Patel, MD, MPH, 1211 21st Ave South, 404 Medical Arts Bldg, Nashville, TN 37212; email: mayur.b.patel@vanderbilt.edu.

Availability of Companion Documents

The following are available:

- Cervical spine collar clearance in the obtunded adult blunt trauma patient: a systematic review and practice management guideline from the Eastern Association for the Surgery of Trauma. Supplemental digital content. 2015. 1 p. Electronic copies: Available from the Journal of Trauma and Acute Care Surgery Web site .
- Kerwin AJ, Haut ER, Burns JB, Como JJ, Haider A, Stassen N, Dahm P, Eastern Association for the Surgery of Trauma Practice Management Guidelines Ad Hoc Committee. The Eastern Association of the Surgery of Trauma approach to practice management guideline development using Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology. J Trauma Acute Care Surg. 2012 Nov;73(5 Suppl 4):S283-7. Electronic copies: Available from the Eastern Association for the Surgery of Trauma (EAST) Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on March 6, 2015. The information was verified by the guideline developer on March 19, 2015.

Copyright Statement

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